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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,449	03/24/2004	Karin Jooss	3802-090-27 CIP	3354
29585	7590	10/24/2006	EXAMINER	
DLA PIPER RUDNICK GRAY CARY US LLP			OUSPENSKI, ILIA I	
153 TOWNSEND STREET			ART UNIT	
SUITE 800			PAPER NUMBER	
SAN FRANCISCO, CA 94107-1907			1644	

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

DETAILED ACTION

1. Applicant's Preliminary Amendment, filed 02/21/2006, is acknowledged.

Claims 11 and 34 have been cancelled.

Claims 1 and 28 have been amended.

Claims 1 – 10, 12 – 33, and 35 – 43 are pending.

Restriction Requirement

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Groups I – XX. Claims 1 – 10 and 12 – 27, drawn to a method for cancer therapy, comprising administering a cytokine-expressing cellular vaccine and a specific additional cancer therapeutic agent, or a specific combination of additional cancer therapeutic agents, wherein the agent or agents are selected from those listed in claim 1, classified in Class 424, subclass 93.21.

Applicant is required to elect a Group drawn to a method comprising administering a single specific cancer therapeutic agent, or a single specific combination of agents, and indicate claims readable thereon, for example:

Group I, claims 1 – 10, 12, 14, 15, 19, 20, and 23 – 27, drawn to a method for cancer therapy, comprising administering a cytokine-expressing cellular vaccine, anti-4-1BB antibody, and docetaxel.

Groups XXI – XXXX. Claims 28 – 33 and 35 – 43, drawn to a composition comprising a cytokine-expressing cellular vaccine and a specific additional cancer therapeutic agent, or a specific combination of additional cancer therapeutic agents, wherein the agent or agents are selected from those listed in claim 1, classified in Class 424, subclass 93.21.

Applicant is required to elect a Group drawn to a composition comprising single specific cancer therapeutic agent, or a single specific combination of agents, and indicate claims readable thereon, for example:

Group XXI, claims 28 – 33, 35, 37, 40, and 41, drawn to a composition for cancer therapy, comprising a cytokine-expressing cellular vaccine, anti-4-1BB antibody, and docetaxel.

3. Groups I – XX are different methods. The methods differ with respect to ingredients, which are patentably distinct because their structures, physicochemical properties and/or mode of action are different, and they do not share a common structure that is disclosed to be essential for common utility. Furthermore, they require non-coextensive searches in the scientific literature. Therefore, each method is patentably distinct, and searching of these Inventions would impose an undue burden.

Groups XXI – XXXX are different products. The products are patentably distinct because their structures, physicochemical properties and/or mode of action are different, and they do not share a common structure that is disclosed to be essential for common utility. Furthermore, they require non-coextensive searches in the scientific literature. Therefore, each product is patentably distinct, and searching of these Inventions would impose an undue burden.

Art Unit: 1644

Groups (XXI – XXXX) and (I – XX) are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case methods for cancer therapy may be practiced by administering compositions which are materially different from those instantly claimed. Such compositions are known in the art (e.g. Herceptin®).

4. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

5. It is noted that the instant claims contain a generic recitation of a “cytokine-expressing cellular vaccine,” as well as a specific recitation wherein the cytokine is GM-CSF. In the event that additional specific cytokines are introduced into the claims during prosecution, they may be treated as non-elected species. Alternatively, additional restriction or Species election may be required.

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise

Art Unit: 1644

include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. *Process claims that depend from or otherwise include all the limitations of the patentable product* will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. *Failure to do so may result in a loss of the right to rejoinder.*

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Art Unit: 1644

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ILIA OUSPENSKI, Ph.D.

Patent Examiner

Art Unit 1644

A handwritten signature in black ink, reading "Ilia Ouspenski". The signature is written in a cursive, flowing style.

October 4, 2006